To: Jackson, Ryan[jackson.ryan@epa.gov]
From: Beck, Nancy
Sent: Tue 5/30/2017 2:42:54 PM
Subject: FW: BNA: EPA to Clear Backlog of New Chemical Approvals by July, 5/30/17

FYI—Jeff Morris had an interview with BNA last week. Thus another good story.

Ex. 5 - Deliberative Process

Nancy

From: Konkus, John
Sent: Tuesday, May 30, 2017 10:12 AM
To: Graham, Amy <graham.amy@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Ferguson, Lincoln <ferguson.lincoln@epa.gov>
Subject: FW: BNA: EPA to Clear Backlog of New Chemical Approvals by July, 5/30/17

Is this something we want to highlight on social media?

From: So, Katherine
Sent: Tuesday, May 30, 2017 10:01 AM
To: AO OPA OMR CLIPS <AO_OPA_OMR_CLIPS@epa.gov>
Subject: BNA: EPA to Clear Backlog of New Chemical Approvals by July, 5/30/17

BNA

http://esweb.bna.com/eslw/1245/split_display.adp?fedfid=112765121&vname=dennotallissues&wsn=49930950

EPA to Clear Backlog of New Chemical Approvals by July

By Pat Rizzuto 5/30/17

The backlog of new chemicals being reviewed by the Environmental Protection Agency is expected to be cleared by July due to staffing, policy and procedural changes the agency has made.

Jeffery Morris, director of EPA's Office of Pollution Prevention and Toxics (OPPT), spoke with Bloomberg BNA about adjustments the agency has made that have cut the backlog of manufacturers' new chemicals requests. The backlog is of pre-manufacture notices (PMNs) the agency is reviewing that currently exceeds its normal volume of about 300 pending requests.

The backlog peaked at about 600 PMNs at the end of 2016 following the overhaul Congress made to the 1976 Toxic Substances Control Act (TSCA) last June, Morris said. The backlog is now less than 150, EPA said.

Getting new chemicals to market helps industry and consumers because the new molecules typically enhance the performance of the products the chemicals make, Morris said in his first interview about the agency's efforts to speed its new chemical reviews. New chemicals often have a better environmental footprint by cutting energy consumption, hazardous waste, water pollution or other environmental benefits when compared to the chemicals they replace, he said.

Critical Change

The biggest change that the EPA's new chemicals office had to adjust to, Morris said, was the amended law's requirement that the agency make a specific conclusion about the risk each new chemical could pose.

Original TSCA did not require the agency to make specific conclusions about a new chemical's risks. If the agency did nothing during the 90 days the statute gives it to complete new chemical reviews, the molecule could be made or imported for any TSCA-regulated use under the 1976 statute. The amended law retains the 90-day review period, but requires the agency to make "affirmative findings" for each chemical.

The new requirement improved the law, because it enhances public confidence in the government's chemical oversight, Morris said.

The new procedures and policies the agency is implementing also should improve regulatory certainty, he said. An agency website lists possible conclusions the EPA can make including that a new chemical:

• Is "not likely to present an unreasonable risk" to the environment or people—including vulnerable or highly exposed populations;

• May pose an unreasonable risk that would be controlled before the chemical could be made or imported; or

• Has insufficient information to allow the agency to make "a reasoned evaluation" of its health

and environmental effects.

Morris described the first six months after amended TSCA as a "real learning curve" as staff figured out how to make those determinations and explain them in ways diverse audiences could understand.

"It was a heavy lift," he said. But, "I'm very happy to say we're confident that by the end of July we will have eliminated the backlog."

Industry Describes Problem

In early April, Cal Dooley, chief executive officer for the American Chemistry Council, described in an Insights article for Bloomberg BNA the problems the agency's initial new chemical delays were causing. New chemical evaluations had "become mired in inefficiencies, causing significant delay for manufacturers," Dooley, whose trade association represents companies including the BASF Corp., the Dow Chemical Co., and Honeywell, wrote.

Arkema Inc., which produces acrylic monomers, additives, hydrogen peroxide, coating compounds and other chemicals, is among the manufacturers that discussed its concerns about the new chemicals program as it met with Congressional lawmakers during the first quarter of 2017.

Arkema urged lawmakers to give the EPA sufficient resources for timely implementation of the amended TSCA's changes, including the new chemical provisions, the company said in a statement provided to Bloomberg BNA.

Giving sufficient EPA resources "can help the agency to evaluate and process the approval of pre-manufacture notices, to allow companies like Arkema to innovate and bring to market new materials that better meet the needs of users and consumers, or that deliver benefits such as enhanced sustainability," the company said.

EPA's Staffing Solutions

The chemicals office tripled the amount of time its scientists focused on new chemicals, Morris said. About 70 scientists work in the program's Risk Assessment Division, he said.

"At any given time about half of those people are involved in some way or other in new chemicals," Morris said. The rest of the time the risk assessors focus on existing chemicals and questions arising in the agency that call for their particular expertise.

The chemical's office could boost risk assessors time on new chemicals, because it hadn't fully ramped up to begin the risk analyses amended TSCA requires it to undertake for chemicals on the U.S. market, he said.

Having reduced the new chemicals backlog, those same scientists are now focused on developing the scope of risk assessments the agency will conduct for 10 existing chemicals,

including solvents. flame retardants and one dye. The scoping documents will describe what health and environmental concerns, exposures and other issues the agency's risk analyses will examine. Amended TSCA requires EPA to complete those scoping documents by June 19.

The agency also temporarily transferred to the new chemicals program about 15 individuals who manage each chemical's review, Morris said. Those individuals work with the agency's scientists, manufacturers and importers who've submitted new chemical requests. The managerial staff will shift back to other duties once the new chemicals backlog is cleared in July, Morris said.

First Major Policy Change

"We've made policy changes that not only reduce the backlog, but make sure a backlog doesn't occur again," he said.

A critical change the agency has made is to approve a new chemical for a particular use or uses its manufacturer or importer intended, along with reasonably foreseeable uses, he said.

If the agency has concerns because the new chemical could be made, used or released into the environment in ways other than what its original manufacturer intended, it will restrict those uses through significant new uses rules, called SNURs, Morris said.

Chemical manufacturers have urged the agency to use this mechanism, commonly called a "non-5(e) SNUR," as it implements amended TSCA just as it had under the original law. That specific provision refers to the section of TSCA that gives EPA oversight of new chemicals and a type of regulation it can issue. The term also refers to the EPA's conclusion that intended or reasonably foreseen uses of a new chemical would not likely present an unreasonable risk, but that other manufacturing methods or uses might, leaving the door open in case other firms employ them.

Initially, the EPA needed time to make sure it could make a legally supportable argument that the amended law allowed it to continue making such findings, Morris said.

"We determined it's legally supportable," provided needed restrictions would be in place before the new chemical was made or imported and that those restrictions protect human health and the environment, Morris said.

Being able to issue non-5(e) SNURs will allow a significant number of new chemicals that had been part of the backlog to get to market, he said.

Two Agency Actions Must Align

Before a new chemical could be made or imported, however, the EPA must align two coupled activities.

First, the agency must work with each manufacturer or importer to determine the manufacturing methods for, environmental releases of, and uses of, the new chemical that would not be likely to pose an unreasonable risk. A consent order negotiated between the agency and the original

manufacturer or importer then binds that specific company to the agreed upon manufacturing and use conditions.

Second, the conditions that the EPA concludes would result in the chemical being unlikely to pose an unreasonable risk must be applied to any subsequent manufacturer or importer that could make the chemicals, Morris said. The agency does that through SNURs.

The chemicals office is developing a strategy to align the two related actions: approving the original manufacturer's request to make a new chemical and issuing a rule that would require subsequent manufacturers to meet any restrictions the original company agreed to, he said.

The goal, Morris said, is to allow the original manufacturer to get a "not likely to pose an unreasonable risk" finding, while making sure restrictions are in place to prevent risks that might occur if other companies made or used the chemical in different ways.

Polymers

Similarly, the EPA is allowing certain polymers to get to market quicker than it did in the initial months after TSCA was amended when they are unlikely to cause health or environmental concerns due to their large size and other characteristics.

Under the original and amended TSCA, EPA has allowed such polymers to be made under what was called a "polymer exemption." That means the company could make the new polymer without filing a new chemicals notice provided the chemical met specified criteria. The EPA's rationale is that that the polymer exemption encourages the manufacture of safer polymers by reducing industry's reporting burden for these types of chemicals. The reduced burden allows the EPA to concentrate its new chemical resources on substances that could pose higher risk, an EPA website explains.

Yet sometimes polymer manufacturers choose to submit new chemical notices. Or perhaps the molecule's characteristics show it could raise concerns if it were made in ways that produced smaller chemicals, called monomers, which could enter and interact with biological systems

The EPA has determined it can allow polymers, which could qualify for the exemption, into commerce with a proviso, Morris said. When the new polymer is added to the TSCA inventory—which lists chemicals that are or have been in U.S. commerce—it will have a flag saying the chemical must be made in ways so that it couldn't be biologically available, Morris said. The EPA announced its first such conditional approval on May 12.

Useful Data For EPA to Get

Another change Morris described has been requested by many chemical makers and the attorneys and trade associations that represent them.

The agency will publicize information manufacturers could submit with their pre-manufacture notices to speed the agency's reviews, he said.

Neither original nor amended TSCA requires manufacturers to submit specific toxicity, exposure or other data when they ask the agency to allow them to make a new chemical.

Faced with a lack of information about use conditions—such as the amount of a chemical that would be released to water, whether workers would be shielded from exposure because the new chemical would be made in a closed system, or whether workers would be required to wear protective gear—the agency makes assumptions. Those "default assumptions" are contained in software the agency uses, for example, to model how much of a chemical may be released in the workplace or what could happen to fish and the bugs they eat if the chemical got into water. To be protective, the agency assumes a new chemical would be released in greater quantities or that exposure is higher than it may be.

The consequence, Morris said, is that the EPA, manufacturers and importers spend time going back and forth working out more realistic use conditions. Depending on how confident a manufacturer is about its potential market for a new chemical, it may chose to pay to generate exposure or other data to prove to the agency that a chemical is less toxic or that exposure to it would be less than the agency assumes. Agency concerns and the cost of generating new data may also prompt a manufacturer to withdraw its new chemical notice rather than face potential controls.

Alerting firms about data needs means "we'll have a much greater chance of receiving information that will allow us to run scientific analyses one time and get companies on the road to commercialization," Morris said.

The EPA also is encouraging chemical makers to meet with agency staff before they submit a pre-manufacture notice, to spotlight data the agency needs before a new chemical's review begins, Morris said.

Katherine So

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U.S. Environmental Protection Agency

Ex. 6 - Personal Privacy

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